

**1954. Misbranding of first aid kits. U. S. v. 594 First Aid Kits. Default decree of condemnation. Product ordered delivered to a charitable institution.** (F. D. C. No. 20234. Sample No. 63642-H.)

**LIBEL FILED:** On or about June 12, 1946, District of New Jersey.

**ALLEGED SHIPMENT:** On or about April 9, 1946, by the H. P. Enterprise Co., from New York, N. Y.

**PRODUCT:** 594 *first aid kits* at Fair Lawn, N. J. Examination showed that each of the kits contained, among other items, vials of tablets designated as "Amphetamine Sulfate—5 MG.," "Atabrine Tablets," and "Wound Tablets." Analytical tests disclosed that the *wound tablets* contained sulfadiazine.

**LABEL, IN PART:** "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

**NATURE OF CHARGE.** Misbranding, Section 502 (j), the products were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (*Amphetamine sulfate tablets*) "Directions: Take one tablet if sleepy or two tablets if extremely fatigued. Repeat this dose in six hours if necessary but do not take more than six tablets in any one week," and (*wound tablets*) "Use—When Hit: Take all tablets. Drink lots of water. \* \* \* Wounds—Take internally by mouth, followed by a large amount of water, 8 Sulfadiazine tablets."

Misbranding, Section 502 (f) (1), (*Atabrine tablets*) the labeling failed to bear adequate directions for use. The following directions in the labeling were not adequate directions for use in the prevention or treatment of malaria: "Use: For Prevention of Symptoms of Malaria. Take first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on two days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in malarial area and continue to take it as long as you are in a malarial area \* \* \* Malaria (Chills and Fever) (Prevention)—Take first dose of Atabrine (1 tablet) in morning and second dose (1 tablet) in the evening after meals on 2 days of each week. Skip two or three days between the days of taking Atabrine. Start to take Atabrine on the first days you are in a malarial area and continue to take it as long as you are in a malarial area."

**DISPOSITION:** July 23, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered delivered to a charitable institution after the destruction of the labels under the supervision of the Food and Drug Administration.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

**1955. Misbranding of Todd's Tonic Bitters, Todd's Laxanodine, and Todd's Iron-tone. U. S. v. Thomas I. Todd (Todd Medicine Co.). Plea of nolo contendere. Fine of \$300 and probation for 3 years.** (F. D. C. No. 16584. Sample Nos. 87011-F, 87012-F, 87135-F.)

**INFORMATION FILED:** November 6, 1945, Middle District of Georgia, against Thomas I. Todd, trading as the Todd Medicine Co., Athens, Ga.

**ALLEGED SHIPMENT:** On or about July 27 and November 25, 1944, from the State of Georgia into the State of Michigan.

**PRODUCT:** Analyses disclosed that the *Tonic Bitters* consisted essentially of sodium salicylate, extracts of plant drugs, including a laxative drug and a bitter drug, alcohol 3.94 percent by volume, and water; that the *Laxanodine* consisted essentially of sodium salicylate, extracts of plant drugs, including a laxative drug and a bitter drug, and water; and that the *Iron-tone* consisted essentially of extracts of plant drugs, including a laxative drug and a bitter drug, a small proportion of salicylic acid, iron acetate (approximately 1.1 percent), and water.

**NATURE OF CHARGE:** *Tonic Bitters*, misbranding, Section 502(a), certain statements on the label of the article, and the statement in the circular enclosed in the package containing the article, "Good Health Is Worth More Than Riches or Gold," were false and misleading since they represented and suggested that the article was a tonic, diuretic, and alterative; that it would be efficacious in the cure, mitigation, treatment, and prevention of diseases of the stomach, kidneys, bladder, bowels, and blood, rheumatism, lumbago, faulty elimination of the kidneys, and affections of the urinary tract; that it was an efficacious tonic to the stomach and alimentary tract; that it would restore vigorous

\*See also No. 1954.

health to puny, run-down people; that it was a curative, health-building tonic which contained medicine that would be efficacious in the cure, mitigation, treatment, and prevention of diseases and ailments of the liver, kidneys, stomach, spleen, and blood; that it would relieve bladder irritation, would drive out poisonous uric acid, would improve the digestion, would heal the irritated conditions of the stomach and intestinal tract; and that it would be efficacious in the cure, mitigation, treatment, and prevention of aches, pains, and weak run-down conditions, constipation, nervousness, sick headaches, pains under the shoulder, kidney and bladder troubles, indigestion and stomach troubles, misery in the back, sides, and limbs, sore and painful back and head, disturbances of sleep, burning and stinging sensation in the bladder, and frequent urination. The article was not a tonic, diuretic, and alterative, and it would not be efficacious for the purposes represented.

*Laxanodine*, misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned circulars accompanying the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of derangements of the liver; that it was a tonic; that it would be efficacious in the cure, mitigation, treatment, and prevention of biliousness, sick headache, acute and chronic indigestion, fevers, jaundice and bowel troubles, constipation, cholera morbus, colics, and teething troubles; that it would be efficacious to restore vigorous health to puny run-down people; that it was a healing medicine prepared from nature's healing herbs; and that it would be efficacious in the cure, mitigation, treatment, and prevention of constipation, sick stomach, nausea and vomiting, hiccups, piles, irritation and soreness of the stomach and bowels, griping and pain in cholera morbus, dysentery and diarrhea, vertigo, colds, flu, stomach, liver and bowel troubles, congestion of the spleen, pain in the side, swelling in the side, high blood pressure, frequent attacks of heart trouble, gastric indigestion, and weak, thin, and emaciated conditions. The article was not a healing medicine prepared from nature's healing herbs, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (f) (2), the article was a laxative, and its labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent and continued use of the article might result in dependence upon laxatives to move the bowels.

*Ironstone*, misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned circulars accompanying the article were false and misleading since they represented and suggested that the article would be efficacious as a tonic; that it was a great strength and blood builder; that it would be efficacious in the cure, mitigation, treatment, and prevention of dropsy, tuberculosis, female weakness, suppressed and painful menstruation, and loss of appetite; that it would be efficacious for building pale, weak, puny people of any age; that it would overcome the cause of anemia; that it would be efficacious in the cure, mitigation, treatment, and prevention of anemia caused by malaria, flu, and other weakening diseases; that it would be efficacious in the cure, mitigation, treatment, and prevention of weakness and emaciation, female troubles, piles, including bleeding piles, badly swollen hands and feet, indigestion, and constipation; that it would be efficacious to restore red corpuscles; that it would enrich the blood, would make puny children grow, would strengthen the feeble and aged and would make weak, flabby muscles firm and strong, would color the cheeks with the pink glow of health, would enable women to enjoy better health, and would be efficacious to aid recovery from pneumonia. The article would not be efficacious for the purposes represented.

Further misbranding, Section 502 (b) (2), the labels of the articles bore no statement of the quantity of the contents; and, Section 502 (e) (2), the labels of the *Laxanodine* and *Ironstone* failed to bear the common or usual name of each active ingredient.

DISPOSITION: June 4, 1946. A plea of nolo contendere having been entered, the court imposed a fine of \$300 and placed the defendant on probation for a period of 3 years.

1956. Misbranding of Interferin. U. S. v. William H. Kropp (Kropp's Prescription Pharmacy). Plea of guilty. Fine, \$1,000. (F. D. C. No. 17865. Sample No. 17385-H.)

INFORMATION FILED: June 7, 1946, Eastern District of Wisconsin, against William H. Kropp, trading as Kropp's Prescription Pharmacy; charging that the defendant on or about April 19, 1945, received in interstate commerce from